Application Number 60/192,198, filed March 27, 2000. The contents of both applications are incorporated herein by reference.

Amendments to the Claims:

Please cancel claims 8, 9, 14, 21, 22, 25, 37, 38, 40, 49, 52, 71, 72, 74, 85, 86 and 88.

REMARKS

I. The Amendments Herein

The first paragraph of the specification has been amended to correct the date the priority applications were filed. The amendments add no new matter.

II. Status of the Claims

Claims 1-7, 10-13, 15-20, 23, 24, 26-36, 39, 41-48, 50, 51, 53-70, 73, 75-84, 89, and 90-93 are pending.

III. Response to the Restriction Requirement

Applicants elect Group I, with traverse. Within Group I, Applicants elect the lungs as the organ of interest, for purposes of claim 10. As shown below, Group I should be rejoined to Groups II-XI, and claim 10 is a Markush group that, under the MPEP, must be examined together.

The Action restricts the 93 claims of the application into more than **2,500 groups**.[1] Applicants believe this restriction of the claims into hundreds of thousands of groups is

[1] The Action initially restricts the claims into 77 groups. But, the Action further requires on page 16, paragraph 8, that "if" the Applicants elect any of the "78" groups [sic, actually 77], they must make an election of one of specific patentably distinct sequences as recited in claims 8, 9, 21, 22, 37, 38, 49, 50, 71, 72, 85, and 86. Claim 8 and the claims tracking it (claims 21, 37, 49, 71, and 85) recite 30 sequences. Claim 9 and the claims tracking it (claims 22, 38, 50, 72. and 86) recite 7 sequences. Multiplying the 77 groups by the 30 sequences is 2310, while multiplying the 77 groups by the 7 sequences of claim 9 and its peers is 539. Adding them together

unsupportable and is contrary to both the MPEP and to applicable law. Accordingly, Applicants traverse the restriction.

A. The Restriction Errs in Adding Recitations to the Independent Claims and to Other Dependent Claims .

The Action restricts numerous claims into multiple groups, by importing recitations in dependent claims into the independent claims. For example, Claim 1 is divided into 11 different groups. The Action states the construct that claim 1 is drawn to a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and places it in Group I. The Action then states that "the construct" recited in claim 11 is viewed as a conjugate, fusion protein, or complex, consisting of a binding component and a biologically active component, such as a nucleic acid, a protein, a radioisotope, a lipid, and the like. According to the Action, these molecules differ with respect to their structure from the ligand recited in claim 1 and "therefore" the restriction has been set forth for each as separate groups. Action, at page 2, paragraph 2. The Action then creates a group of claims 1-10, but also includes claim 1-10 into 10 other groups depending on whether the ligand of those claims further comprises a nucleic acid, a lipid, a protein, or other biologically active molecule.

Claim 1 reads as follows:

1. A ligand that binds specifically to a region of a polymeric immunoglobulin receptor (pIgR) of a cell of an animal, which pIgR when cleaved has a stalk region which remains attached to the cell and a secretory component (SC) which exists in an organ of interest in several forms, provided that the ligand does not substantially bind to the most abundant form of SC present in the organ of interest and provided further that

with the 12-way species election in Group I to reflect the organs recited in Claim 10 adds 11 more. It therefore appears that the restriction requirement would require the Applicants to file some 2,500 applications to capture every embodiment of the 93 claims as filed.

the ligand does not substantially bind to the stalk of said pIgR under physiological conditions.

Claim 11 reads as follows:

11. A ligand of claim 1 which is further defined as comprising a binding component for binding to pIgR and a biologically active component.

Markedly lacking from either claim is a recitation that the biologically active component is a nucleic acid, a lipid, a protein, or other biologically active component. The Action's division of claims 1 and 11 into 11 separate groups, 10 of which are purportedly drawn to different biologically active components therefore rests on importing into claims 1 and 11 recitations from dependent claim 14 that are drawn to specific embodiments of the invention. The Action cites no justification or authority for rewriting claim 1 and 11 by importing into them recitations from a dependent claim. The Action compounds this error by repeating it with respect to each of the other independent claims (except for claim 16, presumably because it does not have any dependent claims). Applicants respectfully request that the Examiner withdraw the restriction requirement with respect to Groups I through XI.

B. By Adding Recitations to the Independent Claims and to Other Dependent Claims, the Action Fails to Read the Claim as a Whole

By reading the recitations of the dependent claims into the base claim, the Action divides the claim up into parts, rather than examining the claim as a whole. The U.S. Court of Appeals for the Federal Circuit, whose rulings the Patent and Trademark Office is obliged to follow, has specifically held that individual claims cannot be divided and examined in part. As the Federal Circuit's predecessor court, the Court for Customs and Patent Appeals ("C.C.P.A.") stated:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the

> applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber, Soder and Boksay, 198 USPQ 328, 331 (C.C.P.A. 1978).[2] *See also In re Haas,* 179 USPQ 623, 624-625 (C.C.P.A. 1973) (*In re Haas I*); and *In re Haas,* 198 USPQ 334, 334-337 (C.C.P.A. 1978) (*In re Haas II*). The Court's concern is particularly appropriate in this case, since the specific types of biologically active components set forth in claim 14 do not necessarily encompass the universe of biologically active components.

Moreover, it has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See In re Weber,* 198 USPQ at 328. The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See id.*; *In re Haas I,* 179 USPQ at 623; and *In re Haas II,* 198 USPQ at 334. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber, 198 USPQ at 334.

Therefore, dividing claims 1 and 11 into 11 groups to be examined on the basis that each group allegedly represents an independent and distinct invention is clearly contrary to

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[2] The Federal Circuit expressly adopted the holdings of the CCPA as precedent of the Federal Circuit.

the requirements set down by the Court. Applicants respectfully request that the Examiner withdraw the restriction requirement with respect to Groups I through XI.[3]

C. The Restriction Does Not Follow the MPEP's Instructions for Examining Linking Claims

The Action's restriction of claim 1 and of claim 11 is not in accord with the practice mandated by the MPEP. Claims 1 and 11 are genus claims, the method of which does not depend on the particular method used. MPEP §809.03 (8th Ed. August 2001, Feb 2003 revision) (all cites to the MPEP herein are to this revision) states that a genus claim that links species claims is a "linking claim." The section further states that such claims are inseparable from the otherwise divisible species and prevent restriction between inventions.[4]

According to the MPEP, where there is a linking claim, a restriction may be imposed. But, the proper practice is require the applicant to elect an invention and to examine the linking claim with the invention elected. "[S]hould any linking claim be allowed, the restriction requirement must be withdrawn." MPEP § 809. Moreover, the MPEP provides a form paragraph to be used in the case of linking claims. See, MPEP § 809.03 at page 800-50. That paragraph provides that the Applicant is entitled to consideration of a reasonable number of disclosed species in addition to the elected species provided (as here) that all the claims to each additional species are written in dependent form or otherwise include all the limitations of an allowed generic claim. The Action fails to note that either claim 1 or claim 11 is a linking claim, and therefore fails to note that the restriction among the various species of organs, as set forth in

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[3] For the sake of good order, Applicants note that the remaining 66 groups corresponding to Groups 1-11 should also be rejoined to their independent claims. The rejoinder of these groups is, however, moot for the time being given the election of Group I herein.

[4] MPEP §809.03 provides:

> There are a number of situations which arise in which an application has claims to two or more properly divisible inventions. . . . but presented in the same case are one or more claims . . . inseparable therefrom and thus linking together the inventions otherwise divisible.
>
> The most common types of linking claims which, if allowed, act to prevent restriction between inventions that can otherwise be shown to be divisible are:
>
> (A) genus claims linking species claims. . . .

claim 10, or of biologically active components, as set forth in claim 14, must be withdrawn if linking claim 1 or linking claim 11 is found allowable.

D. The Restriction Does Not Follow the MPEP's Instructions for Examining Markush Claims

MPEP § 803.02 emphasizes that, since *In re Weber, supra*, it is improper for the Office to refuse to examine what the applicants consider as their invention by restricting a Markush group unless the subject matter in a claim lacks unity of invention. The MPEP section further indicates that if the members of a Markush group are so closely related that a search and examination on the merits can be made without serious burden, however, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. *Id.* In the present case, the individual organs set forth in claim 10 all have a common utility: the administration of the ligands of the invention to any of the organs permits delivery of biologically active components to the organism. Similarly, the biologically active components set forth in claim 14 are all simply delivered by the ligand to the region of the polymeric immunoglobulin receptor defined in claim 1. Their individual therapeutic effect is immaterial to their common delivery. The members of the Markush groups in this case, therefore, are so closely related that there cannot be a serious burden on the Examiner to consider them on the merits together.

The Action takes the position that the organs set forth in claim 10 are different species because "their structure, physiochemical properties and mode of action are different." Action, at page 16, paragraph 9. While it is clear that the organs are different, the Action does not elucidate how these differences apply in the context of the claimed ligands. Moreover, while the Action alleges different searches would be required in the scientific literature, id., it does not even allege, let alone show, that there would be a serious burden on the examiner to search all the members of the Markush group together.

Accordingly, the restrictions set forth in the Action between the members of the Markush groups in claims 10 and 14 do not comport with the MPEP. The restriction should be

reconsidered and, upon reconsideration, withdrawn, at least with respect to Groups I-XI and claims 10 and 14.

E. The Action Incorrectly Divides the Ligands from Constructs Comprising the Ligand

The Action starts the restriction requirement by stating that claim 1 is to a ligand, while claim 11 (among others) is drawn to a construct of the ligand further comprising a biologically active component. Action, at page 2, paragraph 2. The Action's justification for this is that these "molecules differ with respect to their structure from a molecule recited in claim 1." Lacking from the Action is any explanation of why this would define a reason for a proper restriction. Applicants note that the Guidelines set forth in MPEP §803 require the Examiner "to provide reasons and/or examples to support conclusions." In the absence of any appropriate rationale, Applicants submit that the restriction is improper under MPEP § 803.02, as set forth above and should be withdrawn at least with respect to Groups I-XI.

F. The Action Fails to Show that the Inventions are Distinct, and that Restriction is Therefore Appropriate

Most of the allegedly distinct inventions in the Groups set forth in the Action are acknowledged to be classified in the same classes and subclasses. For example, Groups II-XI, XIV-XXIII, XXVII-XXXVI, XXXIX-XLVII, LI-LXII, and LXV-LXXVI are all classified in Class 530, subclass 350 and Class 424, subclass 193.1. The Action maintains that the inventions are distinct because the inventions have acquired a separate status in the art, as shown by their different classifications. The Action further asserts, at page 15, paragraph 7, that

> even though in some cases the classification is shared, a different field of search would be required based on the structurally different products and various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for

the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

While it may be a burden for the examiner to search more than one invention, the point of the classification system is to indicate whether in fact there is more than one invention, as indicated, for example, by the inventions acquiring a separate status in the art. Applicants also note that every search in the biotech arts entails a literature search as well as a patent search. Therefore, the necessity for a literature search cannot by itself indicate that two supposedly "separate" inventions are in fact both separate and distinct.

Moreover, the question is not whether the searches are identical, but whether the searches impose a serious burden on the examiner. As stated by MPEP § 803, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits even though it includes claims to separate and distinct inventions." The fact that two searches may not be precisely identical does not show that there is a serious burden to conduct them.

The Action's position is a tautology: it is an undue burden on the Examiner to search more than one invention and there is more than one invention because there is a serious burden to search them. Applicants respectfully note that this is yet a further reason to rejoin Groups I-XI and to examine these claims together in this proceeding.

G. Summary

In brief, the Action suffers from several serious deficiencies, any one of which is fatal to the restrictions. First, it improperly rewrites claims 1 and 11 by adding recitations not in the claims as presented. Second, it fails to follow proper examination practice, as set forth in the MPEP, regarding the examination of linking claims. Third, the Action restricts members of Markush groups in which the members are so closely related as to permit their examination without a serious burden on the Examiner. For all these reasons, the restriction among Groups I-XI and the requirement for a species election as to claim 10 should be reconsidered and, upon reconsideration, withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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MARKED UP VERSION SHOWING CORRECTIONS

--This application claims priority from United States Provisional Patent Application Number 60/192,197, filed March 27, [2001] 2000, and United States Provisional Patent Application Number 60/192,198, filed March 27, [2001] 2000. The contents of both applications are incorporated herein by reference.--